



### **AMENDMENTS TO THE CLAIMS**

Claim 1 (currently amended). A process for making an implant more suitable for implantation into a recipient, wherein the implant at least partially comprises a soft tissue, the process comprising:

- (a) contacting the implant with a protective agent selected from the group consisting of alcohols and polyols;
- (b) contacting the implant with an oxidizing sterilant; and
- (c) contacting the implant with a rinsing fluid,

further comprising applying tension to the soft tissue at least during part of step (b).

Claim 2 (original). The process of claim 1, wherein at least one of steps (a), (b) or (c) further comprises cyclically increasing and decreasing pressure during the contact with the implant.

Claim 3 (original). The process of claim 1, further comprising:

- (d) contacting the implant with an oxidizing sterilant; and
- (e) contacting the implant with a rinsing fluid.

Claim 4 (original). The process of claim 3, wherein at least one of steps (a) through (e) further comprises cyclically increasing and decreasing pressure during the contact with the implant.

Claim 5 (original). The process of claim 1, further comprising the step of rinsing the implant with an aqueous solution between steps (b) and (c).

Claim 6 (original). The process of claim 1 wherein prior to step (b), the implant contains an amount of the alcohol in the soft tissue sufficient to reduce damage from oxidation to the soft tissue.

Claim 7 (original). The process of claim 1, wherein the rinsing fluid is selected from the group consisting of alcohols, polyols, acetone, water, and mixtures thereof.

Claim 8 (original). The process of claim 1, wherein the rinsing fluid comprises a monohydric alcohol having one to eight carbon atoms.

Claim 9 (original). The process of claim 1, wherein step (b) comprises contacting the implant with an aqueous solution comprising hydrogen peroxide in a concentration range of from about 1% to about 10%.

Claim 10 (original). The process of claim 1, wherein the implant comprises at least one tendon or ligament.

Claim 11 (original). The process of claim 1, wherein the implant comprises a tendon having bone attached thereto.

Claim 12: Cancelled.

Claim 13 (currently amended). A process for making an implant more suitable for implantation into a recipient, wherein the implant at least partially comprises a soft tissue, the process comprising:

(a) contacting the implant with a protective agent selected from the group consisting of alcohols and polyols;

(b) contacting the implant with an oxidizing sterilant; and

(c) contacting the implant with a rinsing fluid,

~~The process according to any of claims 1, 2, 3, 4, 5, or 6~~ further comprising: applying kinematic restraint to the soft tissue during each of steps (a), (b) and (c).

Claim 14 (withdrawn). A process for making an implant more suitable for implantation into a recipient, wherein the implant at least partially comprises a soft tissue, the process comprising:

contacting the implant with a peroxide for less than about 80 consecutive minutes.

Claim 15 (withdrawn). The process of claim 14 wherein the implant is contacted with a peroxide for no more than about 60 consecutive minutes.

Claim 16 (withdrawn). The process of claim 14 wherein the implant is contacted with a peroxide for no more than about 40 consecutive minutes.

Claim 17 (withdrawn). The process of claim 14 wherein the implant is contacted with a peroxide for no more than about 20 consecutive minutes.

Claim 18 (withdrawn). The process of claim 14 wherein the implant is contacted with a peroxide for no more than about 10 consecutive minutes.

Claim 19 (withdrawn). The process of claim 14 wherein the implant is contacted with a peroxide for no more than about 5 consecutive minutes.

Claim 20 (withdrawn). The process of claim 14 wherein the implant is contacted with a peroxide for no more than about 60 consecutive seconds.

Claim 21 (withdrawn). The process according to any of claims 14, 15, 16, 17, 18, 19, or 20, further comprising cyclically increasing and decreasing pressure during at least part of the peroxide contact.

Claim 22 (withdrawn). The process according to any of claims 14, 15, 16, 17, 18, 19, or 20 wherein the implant is contacted with the peroxide at a temperature greater than 42°C.

Claim 23 (withdrawn). The process according to any of claims 14, 15, 16, 17, 18, 19, or 20 wherein the implant is contacted with the peroxide at a temperature of at least about 48°C.

Claim 24 (withdrawn). The process of claim 14 wherein the implant comprises at least one tendon or ligament.

Claim 25 (withdrawn). The process of claim 14 wherein the implant comprises a tendon having bone attached thereto.

Claim 26 (withdrawn). The process of claim 14, further comprising the step of applying tension to the soft tissue at least during part of the contact with the peroxide.

Claim 27 (withdrawn). A process for treating an implant so as to sterilize the implant prior to implantation, the implant comprising a soft tissue, the process comprising:

applying tension to the soft tissue while contacting the soft tissue with a cleaning agent.

Claim 28 (withdrawn). The process of claim 27 wherein from about 0.5 Newton to about 20 Newtons of tension are applied to the soft tissue.

Claim 29 (withdrawn). The process of claim 27 wherein from about 1 Newton to about 10 Newtons of tension are applied to the soft tissue.

Claim 30 (withdrawn). The process of claim 27 wherein from about 3 Newtons to about 5 Newtons of tension are applied to the soft tissue.

Claim 31 (withdrawn). The process of claim 27 wherein the cleaning agent comprises an oxidizing sterilant.

Claim 32 (withdrawn). The process of claim 31 wherein the oxidizing sterilant is a peroxide.

Claim 33 (withdrawn). The process of claim 32, wherein the peroxide is an aqueous solution of hydrogen peroxide.

Claim 34 (withdrawn). The process of claim 27 wherein the cleaning agent comprises a disinfectant.

Claim 35 (withdrawn). The process of claim 27 wherein the cleaning agent is a decontaminating agent.

Claim 36 (withdrawn). The process of claim 27 wherein the cleaning agent comprises a detergent.

Claim 37 (withdrawn). The process of claim 27 wherein the cleaning agent is selected from the group consisting of alcohols, polyols, detergents, and mixtures and combinations thereof.

Claim 38 (withdrawn). The process of claim 27 further comprising the step of contacting the implant with an alcohol before contact with the cleaning agent.

Claim 39 (withdrawn). The process of claim 27, further comprising the step of contacting the implant with a rinsing fluid after contact with the cleaning agent.

Claim 40 (withdrawn). The process according to any of claims 27, 34, 35, 36, or 37, further comprising the step of cyclically increasing and decreasing pressure while the cleaning agent contacts the implant.

Claim 41 (withdrawn). The process of claim 27 wherein the implant comprises at least one tendon or ligament.

Claim 42 (withdrawn). The process of claims 27 wherein the implant comprises a tendon having bone attached thereto.

Claim 43 (withdrawn). An apparatus for applying tension to an implant for treatment, the apparatus comprising:

- (a) fasteners adapted to securely hold first and second ends of an implant;
- (b) a resilient member disposed between the two fasteners;

wherein the resilient member is connected to the fasteners so as to apply a force to the fasteners.

Claim 44 (withdrawn). The apparatus of claim 43, wherein the resilient member is connected to the fasteners so as to force the fasteners apart.

Claim 45 (withdrawn). The apparatus of claim 43, wherein the resilient member is a spring.

Claim 46 (withdrawn). The apparatus of claim 43, further comprising a shaft disposed between the fasteners, and the fasteners are slidable along the shaft.

Claim 47 (withdrawn). The apparatus of claim 43, further comprising a locking mechanism connected to one of the fasteners and adapted to lock the fastener at a desired location along the shaft.

Claim 48 (withdrawn). The apparatus of claim 47, wherein the shaft comprises a channel, and the locking mechanism is a screw adapted to engage the channel of the shaft.

Claim 49 (withdrawn). The apparatus of claim 48, wherein the channel has teeth adapted to engage the screw.

Claim 50 (withdrawn). The apparatus of claim 43, further comprising a visual indicator adapted to indicate a predetermined force is applied by the resilient member.

Claim 51 (withdrawn). The apparatus of claim 43 wherein the visual indicator comprises a scale marked on the shaft.

Claim 52 (withdrawn). The apparatus of claim 43 wherein the visual indicator comprises the interaction between the resilient member and one of the fasteners.

Claim 53 (withdrawn). An apparatus for applying kinematic restraint to an implant for treatment, the apparatus comprising:

- (a) fasteners adapted to securely hold one or more portions of an implant;
- (b) a resilient member disposed between the two fasteners;

wherein the resilient member is adapted to apply a controlled force, torque, displacement, or orientation to the implant.

Claim 54 (withdrawn). The apparatus of claim 53, wherein the fastener is selected from the group consisting of blocks, clips, loops, brackets, ratchets, and combinations thereof.

Claim 55 (withdrawn). The apparatus of claim 53, wherein the fastener is made from a material selected from the group consisting of plastics, metals, ceramics, composites, and combinations thereof.

Claim 56 (withdrawn). The apparatus of claim 53, wherein the fastener is a one-piece fastener.

Claim 57 (withdrawn). The apparatus of claim 53, wherein the fastener is a multi-piece fastener.

Claim 58 (withdrawn). The apparatus of claim 53, wherein the resilient member is selected from the group consisting of coil springs, leaf springs, torsional springs, flexible plastic members, and combinations thereof.

Claim 59 (withdrawn). A process of providing kinematic restraint to a implant comprising a soft tissue, the process comprising:

loading an implant on the apparatus of claim 53; and  
providing kinematic restraint to the implant throughout one or more steps of recovery, processing, packaging, shipment, storage, preoperative preparation, intraoperative, and intraoperative handling of the implant.

Claim 60 (withdrawn). The apparatus of claim 53, wherein the apparatus is constructed of a material selected from the group consisting of medical grade thermoplastics, sheet metals, stainless steels, and combinations thereof.

Claim 61 (withdrawn). A packaging apparatus for an implant comprising:  
the kinematic restraint apparatus of claim 53, and  
a packaging material for sterile packaging an implant, wherein the restraint and the implant are disposed inside the packaging material.



Claim 62 (withdrawn). The packaging apparatus of claim 61 wherein the packaging material comprises a means for holding the restraint or the implant in a predetermined place.

Claim 63 (withdrawn). A process for making an implant more suitable for implantation into a recipient, wherein the implant at least partially comprises a soft tissue, the process comprising:

- (a) contacting the implant with an alcohol;
- (b) contacting the implant with a peroxide for less than about 80 minutes;
- (c) contacting the implant with an alcohol; and
- (d) applying tension to the implant during at least one of steps (a), (b) or (c).

Claim 64 (withdrawn). A process for making an implant more suitable for implantation into a recipient, wherein the implant at least partially comprises a soft tissue, the process comprising:

applying tension to the implant;  
perfusing the tensioned implant with an alcohol; and  
perfusing the tensioned implant with a peroxide for less than about 80 cumulative minutes.

Claim 65 (new). The process of claim 13, wherein at least one of steps (a), (b) or (c) further comprises cyclically increasing and decreasing pressure during the contact with the implant.

Claim 66 (new). The process of claim 13, further comprising:

- (d) contacting the implant with an oxidizing sterilant; and
- (e) contacting the implant with a rinsing fluid.

Claim 67 (new). The process of claim 66, wherein at least one of steps (a) through (e) further comprises cyclically increasing and decreasing pressure during the contact with the implant.

Claim 68 (new). The process of claim 13, further comprising the step of rinsing the implant with an aqueous solution between steps (b) and (c).

Claim 69 (new). The process of claim 13 wherein prior to step (b), the implant contains an amount of the alcohol in the soft tissue sufficient to reduce damage from oxidation to the soft tissue.

Claim 70 (new). The process of claim 13, wherein the rinsing fluid is selected from the group consisting of alcohols, polyols, acetone, water, and mixtures thereof.

Claim 71 (new). The process of claim 13, wherein the rinsing fluid comprises a monohydric alcohol having one to eight carbon atoms.

Claim 72 (new). The process of claim 13, wherein step (b) comprises contacting the implant with an aqueous solution comprising hydrogen peroxide in a concentration range of from about 1% to about 10%.

Claim 73 (new). The process of claim 13, wherein the implant comprises at least one tendon or ligament.

Claim 74 (new). The process of claim 13, wherein the implant comprises a tendon having bone attached thereto.